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| 10/713,772 | 11/14/2003 | Yoshihiro Mori | 09496/0200199-US0 | 8762 |

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| EXAMINER | |
|---|---|
| CRAIG, PAULA L | |
| **ART UNIT** | **PAPER NUMBER** |
| 3761 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/713,772 | MORI ET AL. | |
| | Examiner | Art Unit | |
| | Paula L. Craig | 3761 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *21 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-3,8 and 9* is/are pending in the application.

4a) Of the above claim(s) *9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Response to Arguments*

1. For Claims 1-3 and 8, Applicant's arguments filed August 21, 2007 have been fully considered but they are not persuasive. Applicant argues that the function of the Brugger device is distinct from the claimed device. The function of the Brugger device is primarily proper fluid balancing for the patient, which it accomplishes by monitoring blood concentration in the arterial and venous blood circuits, as well as the blood flow rate of the blood pump and the blood purifying rate of the blood purifier (Brugger, col. 7, lines 26-31, col. 21, lines 24-53, col. 24, lines 7-34, col. 30, lines 30-49). The function of Applicant's device is the same.

2. Applicant argues that when the determined fluid reduction ratio differs from a desired ratio, the Brugger device adjusts a flow restrictor to eliminate the difference, instead of reporting a trouble condition identifying that at least one of the blood pump and the blood purifier is malfunctioning. However, Brugger clearly teaches that trouble conditions such as leaks exist and should be reported (col. 6, lines 53-59, col. 7, lines 39-43, col. 24, lines 38-45, col. 26, lines 7-11, col. 31, lines 9-15). In light of Brugger's teaching of reporting leaks and other trouble conditions, it would be obvious where the difference between the measured values and the theoretical value was greater than expected, to signal a problem in the system.

3. Applicant argues that the claimed device has the advantage of being simpler than prior art systems, in that fewer pressure sensors are required to detect a

degradation in the performance of the blood pump and the blood purifier. However, the claims do not limit the number of pressure sensors. Applicant's specification also indicates that more than one method may be used to diagnose a trouble condition, such as visual observation of leaks (specification, page 29, lines 2-4).

### *Specification*

4. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification does not teach which of the variables and equations disclosed in pages 12-30 of the specification corresponds to the claimed second measurement value, the second theoretical value, the difference between the second measurement value and the second theoretical value, the adjusted blood flow rate, and the second predetermined acceptable ratio difference.

### *Claim Objections*

5. Claim 1 is objected to because of the following informalities: In Claim 1, line 20, "the predetermined" should be "the first predetermined". In Claim 8, line 20, "second first" should be "second". Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

6. Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not

described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The specification does not teach the reporting unit being configured to report the trouble condition for the blood purifier when the difference between the second measurement value and the second theoretical value is larger than the second predetermined ratio difference. The specification also does not teach the reporting unit being configured to report the trouble condition for the blood pump when the difference between the second measurement value and the second theoretical value is not larger than the second predetermined acceptable ratio difference.

***Claim Rejections - 35 USC § 103***

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brugger (US 6,554,789).

9. For Claim 1, Brugger teaches a blood purification device having a blood circuit with an arterial blood circuit and a venous blood circuit (Fig. 11, col. 1, lines 15-17, and col. 9, line 24 to col. 10, line 24). A blood pump is disposed in the arterial blood circuit (blood pump 92, Fig. 11, col. 10, lines 1-17). A blood purifier is connected between the arterial blood circuit and the venous blood circuit, and configured to purify blood flowing in the blood circuit (hemofilter 34, Fig. 11 and col. 5, lines 58-64). A first measuring unit is disposed in the arterial blood circuit configured to measure the blood concentration of

the arterial blood circuit (upstream sensor measuring pre-treatment hematocrit, col. 24, lines 8-14). A second measuring unit is disposed in the venous blood circuit and configured to measure a blood concentration of the venous blood circuit (downstream sensor for post-treatment hematocrit, col. 24, lines 14-21). Brugger teaches a calculating unit configured to calculate a first measurement value and a first theoretical value, the first measurement value referring to a ratio of the blood concentrations measured by the first measuring unit and the second measuring unit (col. 24, lines 21-34, col. 30, lines 30-49). Brugger also teaches the first theoretical value referring to a blood concentration ratio obtained by a formula using a preset blood flow rate and the blood purifying rate of the blood purifier as parameters (col. 21, lines 24-53 and col. 24, lines 21-31). Brugger teaches an evaluation unit (col. 21, line 1 to col. 22, line 59, col. 24, lines 21-43, col. 31, lines 9-18). Brugger teaches a reporting unit configured to report a trouble condition for at least one of the blood pump and the blood purifier when appropriate (col. 24, lines 35-45, col. 26, lines 7-11 and 30-52, col. 31, lines 9-18). Brugger teaches that the device is capable of detecting leaks (col. 6, lines 53-59, col. 7, lines 39-43; note that Applicant's specification teaches that leaks are one of the trouble conditions to be detected by the sensors, see specification, pages 13 and 31). Brugger does not expressly teach the evaluation unit evaluating whether a difference between the first measurement value and the first theoretical value is larger than a first predetermined acceptable ratio difference. Applicant's specification does not disclose that the evaluation unit evaluating whether a difference between the first measurement value and the first theoretical value is larger than a first predetermined acceptable ratio

difference serves any stated purpose or solves any particular problem as compared to the prior art. Various mathematical approaches exist for calculating whether a pair of sensors measuring a concentration are producing the expected results; the effectiveness of each approach from the patient or clinician's point of view depends not only on the precise mathematical formula used, but also on the limits considered tolerable. Applicant has not disclosed that the process of comparing ratios produces any differences from the prior art in the device's output to the patient. It is well known in the art of feedback sensors to report a trouble condition when the theoretical values produced by a sensor do not match the expected results within certain limits. Given that Brugger teaches all the structural limitations of the claims, including a pair of measurement units measuring blood concentration in the arterial and venous blood circuits to detect leaks and other trouble conditions, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Brugger to use ratio differences to calculate when the theoretical values differ enough from the measured values to determine that a trouble condition exists.

10. For Claim 2, Brugger teaches a blood purifier connected between the arterial blood circuit and the venous blood circuit (hemofilter 34, Fig. 11 and col. 5, lines 58-64). A water removing means is connected to the blood purifier for removing water from the blood flowing in the blood purifier (ultrafiltration and removal of waste fluid, col. 6, lines 43-60, col. 7, lines 26-30, col. 20, lines 41-67, col. 21, line 24 to col. 22, line 3, and col. 23, line 43 to col. 24, line 34). The purifying rate is the same as the water removal rate of the water removing means (col. 21, line 24 to col. 24, line 34).

11. For Claim 3, Brugger teaches a substitution fluid supplying means disposed to supply substitution fluid into the blood circuit (replacement fluid, col. 1, lines 37-42, col. 6, lines 1-7, and col. 20, lines 47-54). Brugger teaches a calculating means for calculating the ratio of the blood concentrations calculated as a theoretical value by the designated formula using the substitution fluid supplying rate preset for the substitution fluid supplying means and a filtration rate for the blood purifier in addition to the preset blood flow rate and the preset water removal rate as parameters (col. 6, lines 43-63, col. 20, line 41 to col. 22, line 59, and col. 23, line 43 to col. 24, line 34). Brugger teaches the reporting unit being configured to report a trouble condition for at least one of the blood pump, the blood purifier and the substitution fluid supplying unit (col. 24, lines 35-45, col. 26, lines 7-11 and 30-52, col. 31, lines 9-18).

***Conclusion***

Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paula L. Craig whose telephone number is (571) 272-5964. The examiner can normally be reached on M-F 8:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paula L Craig
Examiner
Art Unit 3761

PLC

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SUPERVISORY PRIMARY EXAMINER